UPDATE

Consumers Advised to Stop Using Ephedra Products Immediately

The Food and Drug Administration (FDA) has issued a consumer alert on the safety of dietary supplements containing ephedra and has notified manufacturers of its intent to publish a final rule on dietary supplements containing ephedrine alkaloids. The rule will state that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury.

Under the Dietary Supplement Health and Education Act of 1994, the FDA bears the burden of proof to show that a dietary supplement presents a significant or unreasonable risk to prevent it from being marketed; in contrast, for drugs that have similar pharmacologic properties to ephedra, manufacturers bear the burden of proof of showing that the drug is safe and effective before it can be marketed.

Ephedra, also called Ma huang, is a naturally occurring substance derived from botanicals. Its principal active ingredient is ephedrine, which when chemically synthesized is regulated as a drug. In recent years ephedra products have been extensively promoted for use to aid weight loss, enhance sports performance, and increase energy. The FDA's concerns about dietary supplements containing ephedra arise in part from ephedra's mechanism of action in the body.

Ephedra is an adrenaline-like stimulant that can have potentially dangerous effects on the heart. Recent studies have also confirmed that ephedra use raises blood pressure and otherwise stresses the circulatory system, effects that have been conclusively linked to significant and substantial adverse health effects like heart problems and strokes.

The FDA has sent 62 letters to firms manufacturing and marketing these dietary supplement products containing ephedra and ephedrine alkaloids alerting them that it intends to issue a final rule prohibiting their sale, which will become effective 60 days after its publication.

To review additional materials relating to dietary supplement products containing ephedra and ephedrine alkaloids visit the U.S. Food and Drug Administration at www.fda.gov.

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